REMARKS

Claims 8-10 and 12-27 are pending. Claims 1-7 and 11 were previously cancelled without prejudice to or disclaimer of the underlying subject matter. No claim amendments have been presented. As such, no new matter enters by way of the present response.

1. Claim Rejections – 35 U.S.C. § 101

Claims 8-10 and 12-27 stand rejected under 35 U.S.C. § 101, because the claimed invention allegedly lacks patentable utility. Office Action at page 2. Applicants respectfully traverse this rejection.

The specification provides a specific, substantial, and credible utility for the claimed microarrays. For example, the specification clearly asserts that the microarrays of the present invention can be used for analyzing biological samples for the presence of maize nucleic acid sequences relating to genes expressed during anthesis or for high-throughput monitoring of gene expression of such genes. *See, e.g.,* specification at page 56, lines 5-17, page 59, line 18 through page 60, line 16, page 61, lines 4-10 and page 92, lines 8-14. The skilled artisan would have understood the utility of the claimed microarray based on such a disclosure. In addition, the claimed microarray allows for customization such that the skilled artisan can design the claimed microarrays to a given set of requirements determined by the artisan. One of ordinary skill in the art would recognize that the claimed microarrays have utility, for example, to determine whether a biological sample contains maize nucleic acid sequences or hybridizing homologues upon

reading the present specification. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner argues, however, that '[t]he claim combination of nucleic acids comprised on a substrate or as a microarray is not supported by a substantial utility because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid." Office Action at page 4. The Office asserts that "[u]nless the array, or the probes found on the array (i.e. nucleic acids), are specific for a certain disease, condition, or certain agronomically significant traits, the nucleic acids [are] only useful for conducting further research to find a substantial utility." *Id.* at page 5. The Examiner appears to support this assertion by alleging that there "is no evidence that LIB189 is a subtractive library" and that "there is no evidence that any of the nucleic acids comprised on the claimed microarray are expressed only at the time of 'anthesis,' only in leaf tissue, or only in *Zea mays* plant having the RX601 genotype." *Id.* The Examiner has provided no support for the assertion that the genes can be expressed only during a given condition or must be specific to a certain disease or agronomic trait to satisfy the utility requirement. As previously stated, the claimed microarrays contain nucleic acid sequences from maize corresponding to genes expressed during anthesis. As such, the claimed microarrays can be used, for example, for analyzing biological samples for the presence of maize nucleic acid sequences relating to genes expressed during anthesis or for high-throughput monitoring of gene expression of such genes without the need for further research to determine whether the sequences are expressed exclusively during anthesis.

Moreover, the Examiner appears to focus on the utility of the individual nucleic acid sequences contained on the claimed microarray. Claims must be considered as a

whole in determining compliance with § 101. *Diamond v. Diehr*, 450 U.S. 175, 188, 209 U.S.P.Q. 1, 9 (1981). It is inappropriate to dissect claims and consider some elements while ignoring others. *Id.* The Office's rejection of the claims continues to focus on the function of the proteins encoded by individual nucleic acid sequences recited in the Markush group on the claimed microarray. Applicants respectfully submit that they are not claiming recited nucleic acid sequences in the abstract. Applicants have disclosed nucleic acid sequences obtained from maize. The claims however are not limited to the nucleic acid sequences, but are directed as a whole to microarrays that comprise, *inter alia*, various nucleic acid sequences selected from the recited Markush group. Accordingly, the Office's arguments that the patentability of the claims is based on the utility of individual nucleic acid sequences alone is improper.

Moreover, the Office has acknowledged that microarrays in general have a specific and substantial utility by way of their "utility for being able to analyze a plurality of nucleic acid samples simultaneously." Examiner's Answer dated May 23, 2003 at page 8 and *see,* Board Decision mailed November 22, 2005 at page 10. The claimed microarrays similarly have the ability to analyze a large number of nucleic acid molecules in a sample simultaneously, for example, for the presence of maize nucleic acid sequences expressed during anthesis within the sample. The skilled artisan would recognize that such microarrays can be useful in identity preservation programs.

In addition, the Office has acknowledged that the in the Fodor and Pirrung patents, "the skilled artisan is free to select the relevant reagent (e.g., nucleic acid) of their choice to attach to the array." Board Decision at page 10. Claims 8 and 12-27 similarly allow the skilled artisan to design or customize a particular microarray tailored to the

specific requirements of the artisan. The claimed microarrays can be tailored to a given set of requirements while providing sequences selected from the recited Markush group that can act, for example, as a control to test technical performance of the array.

The "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met this part of the bargain – the present specification discloses microarrays which, in their current form, provide at least one specific benefit to the public, for example, use to analyze biological samples for the presence of maize nucleic acid sequences. *See, e.g.* Specification at page 59, lines 18-24. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The Federal Circuit has recently provided guidance as to the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir, 2005). First, the Court indicated that the specification disclose "that an invention is useful to the public as disclosed in its current

form." *Id.* at 1371. Second, the Court further noted that the specification "also show that that claimed invention can be used to provide a well-defined and particular benefit." *Id.* Applicants have provided microarrays which are shown in the specification to be useful in analyzing biological samples for the presence of maize nucleic acid sequences. Such a use is sufficient to satisfy the utility standard. *Id.*

The specification discloses specific and substantial uses for the claimed micro-arrays, including use to analyze biological samples for the presence of maize nucleic acid sequence homologues (*see, e.g.,* specification at page 59, line 18 through page 60, line 26, and page 21, lines 11-17) and in high-throughput monitoring of gene expression in a corn plant (*see, e.g.*, specification at page 59, line 25 through page 60, line 16 and page 61, lines 4-10). Moreover, because one skilled in the art may design a microarray comprising a substrate with a variety of molecules characterized by different sequences from the recited Markush group, *see, e.g.,* claim 8, the claimed microarrays may be varied or customized to identify or screen for a particular nucleic acid molecule or molecules as designated by the designer. *See, e.g.,* Petition under 37 C.F.R. § 1.144, filed January 10, 2003, at pages 7-10. The Office argues that this utility, like many of the asserted utilities, is not specific or substantial, *see* Final Action at page 5, but does not provide any support (legal or factual) for the proposition that screening large populations of nucleic acids using the claimed microarrays is not a legally sufficient utility.

One of ordinary skill in the art would recognize that the claimed microarrays have utility, for example, to analyze biological samples for the presence of maize nucleic acid sequences or for high-throughput monitoring of gene expression in a corn plant. These utilities are immediately apparent for the claimed microarrays without further research.

The claimed microarrays have been asserted to be useful in analyzing biological samples for the presence of maize molecules and for high-throughput monitoring of gene expression in a corn plant. These utilities provide a well-defined and particular benefit, *e.g.* to identify maize nucleic acid molecules in a sample, and these utilities are immediately useful to the public as disclosed in their current form. Accordingly, the assertion of the use of the claimed microarrays to analyze such samples satisfies the utility requirement of 35 U.S.C. § 101.

Applicants have disclosed a specific, substantial and credible utility for the claimed microarrays. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

2. Claim Rejections – 35 U.S.C. § 112, first paragraph, enablement

Claims 8-10 and 12-27 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.,* an invention with no utility cannot be enabled). Applicants respectfully traverse this rejection and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the specification teaches a person of ordinary skill to make and use the claimed microarrays. Accordingly, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

3. Claim Rejections – 35 U.S.C. § 112, first paragraph, written description

Claims 8-10 and 12-27 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at page 8. Applicants respectfully traverse this rejection.

Despite the Examiner's admission that "[t]he claimed SEQ ID Numbers meet the written description and enablement provisions of 35 U.S.C. § 112, first paragraph" (Office Action at pages 8-9), the Examiner alleges that "[t]he specification provides insufficient written description to support the genus encompassed by the claims." Office Action at page 9. The Examiner alleges that "it is not apparent from the specification that the claimed SEQ ID Numbers contain a full open reading frame, the claimed nucleic acids of SEQ ID Numbers read on cDNAs of full open reading frame." *Id.* In short, the Examiner argues that "[w]ith the exception of the recited SEQ ID Numbers, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides." *Id.*. This is not a proper basis for a written description rejection of a "comprising" claim. If it was, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed microarrays comprising the claimed genera of nucleic acid molecules.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually in-

vented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession a microarray comprising nucleic acid sequences selected from the recited SEQ ID NOs, and therefore, the claimed invention.

Applicants have provided the nucleotide sequences recited by the claims, *e.g.*, SEQ ID 5776, 5781, 5782, 5783, 5785, 5787, 5800, 5804, 5815, 5818, etc., and have disclosed microarrays comprising such sequences, and have thus established possession of the claimed invention. Moreover, the present application describes more than just microarrays including the nucleotide sequences required by the claims. For example, it describes vectors comprising the claimed nucleic acid molecules, (*see, e.g.,* specification at page 67, line 14 through page 74, line 11) as well as plants transformed by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 74, line 16 to page 82, line 24). Thus, the fact that the claims at issue are intended to cover microarrays comprising nucleic acid molecules that include the recited sequences joined with additional sequences, or complements of the recited sequences does not mean that Applicants

were any less in possession of the nucleic acid molecules of the claimed microarrays.[1] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the claimed microarrays and the nucleic acid sequences of the claimed microarrays. For example, it describes how to make the nucleotide sequences and the libraries from which they were originally purified (specification at page 33, line 6 through page 39, line 25, and Examples 1-2). In addition, one of ordinary skill in the art has the ability to make and use the claimed microarrays based on the disclosure of the present specification, as well as envision a nucleic acid molecule that is complementary to any of the nucleic acid molecules of the claimed microarrays. Furthermore, the addition of extra nucleotides or detectable labels to the sequences present on the claimed microarrays is readily envisioned by one of ordinary skill in the art upon reading the present specification,[2] in particular at page 17, lines 20-24 (describing sequences with labels to facilitate detection); at page 62, line 8 through page 63, line 2 (describing site-directed mutagenesis of nucleic acid molecules); and at page

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[1] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[2] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

86, line 22 to page 87, line 3 (citing references describing the construction, manipulation and isolation of macromolecules). Moreover, it is well established that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (CCPA 1981)).

The Examiner asserts that "[w]ith the exception of [the] recited SEQ ID Numbers, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides." Office Action at page 9. The Examiner appears to assert that each nucleic acid molecule within a genus must be described by its complete structure. Such as assertion is totally unfounded. "There is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." *Falko-Gunter Falkner, et al. v. Stephen C. Inglis, et al.* 05-1324 slip op. at page 14 (Fed. Cir. May 26, 2006). The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) as recently amplified by *Capon v. Eshhar*, 418 F.3d 1349, 76 U.S.P.Q. 1078 (Fed. Cir. 2005). Applicants have satisfied that test for written description.

The claimed microarrays comprise combinations or collections of several genera of nucleic acid molecules. Each genus of nucleic acid molecules on the claimed microarray comprise sequences that are complementary to at least one particular enumerated nucleotide sequence, for example., SEQ ID NOs: 5776, 5781, 5782, 5783, 5785, 5787,

5800, 5804, 5815, 5818, etc. Applicants have disclosed common structural features for each genus of nucleic acid molecules, for example, SEQ ID NO: 5776. The respective common structural feature (*i.e.,* the complement or complements to a nucleotide sequence or sequences recited in the present claims) is shared by every nucleic acid molecule which may be included in a claimed microarray comprising a particular nucleic acid molecule; and the nucleic acid sequence of that nucleic acid molecule distinguishes the members of that genus of nucleic acid molecules from non-members. For example, if a microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence of SEQ ID NO: 5782, then it is a member of the claimed genus of microarrays comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence of SEQ ID NO: 5782. If a microarray does not comprise a substrate with a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence of SEQ ID NO: 5782, then it is not a member of that claimed genus.[3] The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of

[3] The same argument applies with equal force to every genus of the nucleic acid molecules that may be included in the claimed microarrays.

a claimed microarray as such – it either contains the nucleotides of SEQ ID NO: 5782 or it does not. One skilled in the art would clearly know if a microarray comprises a substrate with a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising any one or more of the recited nucleotide sequences. The fact that a nucleic acid molecule may comprise additional sequences, variations, or a full-length cDNA is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

In sum, because the specification demonstrates that Applicants had possession of the claimed microarrays, and have provided an adequate description of the claimed genera of microarrays comprising nucleic acid molecules that are complementary to a nucleic acid molecule comprising one of the recited SEQ ID NOs, the specification satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, and the rejection of claims 8-10 and 12-27 is improper and should be withdrawn. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned at (202) 942-5000 should any additional information be necessary for allowance.

Respectfully submitted,

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